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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,852	06/27/2005	Kenji Okajima	OKAJIMA1	2332

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EXAMINER	
AEDER, SEAN E	

ART UNIT	PAPER NUMBER
1642	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,852	OKAJIMA ET AL.	
	Examiner	Art Unit	
	Sean E. Aeder	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *8-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/13/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Amendments and Remarks filed 6/12/07 in response to the Office Action of 12/13/06 are acknowledged and have been entered.

Claims 7-15 have been added by Applicant.

Claims 1-15 are pending.

Claims 8-15 have been withdrawn for being directed to an invention that is independent or distinct from the invention originally claimed (Election/Restriction).

Claims 1-6 have been amended by Applicant.

Claims 1-7 are currently under examination.

The following Office Action contains New Rejections necessitated by amendments.

Election/Restrictions

Newly submitted claims 8-15 are directed to an invention that is independent or distinct from the invention originally claimed. Originally claims 1-6 are drawn to an inventive group comprising a composition comprising as a main active ingredient Activated Protein C (Group I), while newly added claims are drawn to an inventive group comprising a method of administering Activated Protein C (Group II). The inventions of Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, as they lack the same or corresponding special technical features for the following reasons: The technical feature linking groups I-II appears to be that they all relate to the special technical feature of Activated Protein C.

However, Ogata et al (US Patent 5,831,025) teaches Activated Protein C. Therefore, the technical feature linking the inventions of groups I-II does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art. Accordingly, groups I-II are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 8-15 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Objections Withdrawn

All objections are withdrawn.

Rejections Withdrawn

The rejection of claim 3 under 35 U.S.C., second paragraph, is withdrawn.

The rejection of claims 1-6 on the ground of nonstatutory obviousness-type double patenting, as being unpatentable over claims 1-3 and 7-9 of U.S. Patent No. 5,831,025, is withdrawn. The rejection was regrettably made in error since U.S. Patent No. 5,831,025 was published more than a year prior to the effective filing date of the instant application (see MPEP 804.01).

Response to Arguments

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 remain rejected under 35 U.S.C. 102(b) as being anticipated by Ogata et al (U.S. Patent 5,831,025; 11/3/98) for the reasons stated in the Office Action of 12/13/06 and for the reasons set-forth below.

The Office Action of 12/13/06 contains the following text:

"...It is noted that statements of intended purposes or uses are not considered limitations because they merely state an intended use of the invention rather than any distinct definition of any of the claimed invention's limitations (see Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999)). Recitation of statements describing the claimed product as a medicament intended to treat a condition are not given patentable weight and are not limitations to the claims. Therefore, claims 1-6 are drawn to any product having Activated Protein C as the main active ingredient.

Ogata teaches purified Activated Protein C and a process for preparing Activated Protein C (see claims 1-11, in particular)."

In response to the Office Action of 12/13/06, Applicant amended independent claim 1 to recite "...the activated protein C being present in an amount sufficient for improving prognostic survival in therapy of a malignant tumor, and the medicament being in unit dosage form". Applicant further argues that Ogata et al does not teach activated protein C being present in an amount sufficient for improving prognostic survival in therapy of a malignant tumor, and the medicament being in unit dosage form.

The amendments to the claims and the arguments found in the Response of 6/12/07 have been carefully considered, but are not deemed persuasive. Ogata et al teaches preparing 5392.7 U/mg adjusted to 600 U/ml of activated protein C prepared from a fixed volume (100 L) of industrial scale fresh frozen human placenta to be used for therapeutic applications (see Example 3, in particular). Thus, as indicated by instant claim 6, the preparation taught by Ogata et al would be an amount sufficient for improving prognostic survival in therapy of a malignant tumor. Further, said preparation reads on being in a unit dosage form.

Claims 1-6 remain rejected under 35 U.S.C. 102(b) as being anticipated by Walker (The Journal of Biological Chemistry, June 1980, 255(12):5521-5524) for the reasons stated in the Office Action of 12/13/06 and for the reasons set-forth below.

The Office Action of 12/13/06 contains the following text:

"Walker teaches purified Activated Protein C and a process for preparing Activated Protein C (see paragraph bridging page 5521-5522, in particular)."

In response to the Office Action of 12/13/06, Applicant amended independent claim 1 to recite "...the activated protein C being present in an amount sufficient for improving prognostic survival in therapy of a malignant tumor, and the medicament being in unit dosage form". Further, the Response of 6/12/07 states: "Applicants do not see that Walker discloses a medicament in unit dosage form in an amount effective for improving prognostic survival in therapy of a malignant tumor, wherein the main active ingredient of the medicament is Activated Protein C".

The amendments to the claims and the arguments found in the Response of 6/12/07 have been carefully considered, but are not deemed persuasive. Walker teaches preparing a fixed volume of Activated Protein C from a fixed amount of Protein C (pages 5521-5522, in particular). Although Walker not specifically teach said preparation is in an amount sufficient for any improvement to the prognostic survival in therapy of a malignant tumor, the claimed product appears to be the same as the prior art, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on Applicant to prove that the claimed product is different from that taught by the prior art and to establish patentable differences. See In re Best 562F .2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2nd 1992 (PTO Bd. Pat. App. & Int. 1989).

New Rejections Necessitated by Amendments

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Newly added claim 7 is rejected under 35 U.S.C. 102(b) as being anticipated by Esmon and Comp (EP 0 489 048 B1; December1997).

Esmon and Comp teaches a medicament comprising as a main active ingredient inactivated Activated Protein C being present in an amount sufficient for improving prognostic survival in a therapy of a malignant tumor by "killing" tumors and being present in a "dosage" form (see lines 28-46 of page 4 and claim 1, in particular). It is noted that "inactivated" Activated Protein C is a species of Activated Protein C. Further, by functioning as a compound that blocks the Protein C system (see lines 28-46 of page 4, in particular), inactivated Activated Protein C reads on an "activate ingredient". Esmon and Comp further teaches said medicament combined with a chemotherapeutic (see lines 28-46 of page 4 and claim 1, in particular).

Summary

No claim is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SEA

/Misook Yu/ Misook Yu
Primary Examiner, Art Unit 1642